COVIDIEN

SEP 2 8 2012

510(k) Summary K 121806

Date summary prepared: 31-Aug-2012

510(k) Submitter/Holder

Covidien llc
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Contact

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Name of Device

Trade Name:	Bedside Respiratory Patient Monitoring System
Catalog Numbers:	GR101704, GR101704-RR
Common Name:	Pulse oximeter
Classification Name:	***oximeter*** (21 CFR § 870.2700, class II, DQA); ***monitor, breathing frequency*** (21 CFR § 868.2375, class II, BZQ)

Purpose of Submission

The purpose of this submission is to introduce the Covidien Nellcor Bedside Respiratory Patient Monitoring System which effectively integrates Respiration Rate software parameter into a pulse oximetry monitor whose design is fundamentally similar to the proposed predicate. The intended use of the Bedside Respiratory Patient Monitoring System is the same as that of the predicate with the addition of the use for the continuous non-invasive monitoring of respiration rate in adult patients.

This submission followed the "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, 2005," the "Guidance for Industry on General / Specific Intended Use,1998," and the "Draft Guidance for Industry and FDA Staff: Factors to Consider when Making Benefit-Risk Determinations in Medical Device Premarket Review, 2011."

Predicate Devices

Bedside Respiratory Patient Monitoring System was compared and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Trade Name:	N-600x Pulse Oximeter with Oximax SPD Alert
Device Common Name:	Oximeter
510(k) Number:	K083325 (cleared 3/2009)
Manufacturer:	Covidien, formerly Nellcor, a division of Tyco Healthcare
Trade Name:	Covidien Respiration Rate Software
Device Common Name:	Monitor, breathing frequency
510(k) Number:	K111933 (cleared 3/2012)
Manufacturer:	Covidien, formerly Nellcor, a division of Tyco Healthcare

Device Description

The Covidien Nellcor Bedside Respiratory Patient Monitoring System is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by use of one of a range of compatible Nellcor OxiMax oxygen transducers (sensors). The Bedside Respiratory Patient Monitoring System displays digital values of SpO_2 and pulse and respiratory rate. Pulse amplitude is displayed by means of a "blip bar" presentation or plethysmographic waveform. The Bedside Respiratory Patient Monitoring System can be powered by an internal power supply operating on AC from a standard electrical utility receptacle (from 80VAC to 264VAC) or alternatively by an integral sealed 7.2V, 83W/hr rechargeable lithium-ion battery. The Nellcor OxiMax Bedside Respiratory Patient Monitoring System is intended for prescription use with adult, pediatric and neonatal patients in hospitals, hospital-type facilities, and intra-hospital transport.

Intended Use

The Nellcor™ Bedside Respiratory Patient Monitoring System is a portable pulse oximeter intended for prescription use only as a continuous non-invasive monitor of arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport. The OxiMax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The Respiration Rate parameter, when used in conjunction with the Nellcor Bedside Respiratory Patient Monitoring System and Nellcor Respiratory Sensor, is intended to be used for the continuous non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

Technological and Performance Characteristics

The Bedside Respiratory Patient Monitoring System features the same performance characteristics as the predicate K083325, N-600x Pulse Oximeter with Oximax SPD Alert. There are no significant changes to the function of the device other than the addition of the respiration rate software as an optional parameter for use on the finished device.

Performance Data

The design of the Bedside Respiratory Patient Monitoring System features the same internal printed circuit board assembly as the predicate device thus performance data to demonstrate saturation and pulse rate accuracy, and SPD are unchanged and the associated information provided in K060576 and K083325 are applicable to the device subject of this submission. Integration of Covidien Respiration Rate Software has not resulted in any change to the software algorithm which calculates patient respiration rate based upon oximetry photoplethysmography data, therefore performance data to respiration rate are unchanged and the associated information provided in K111933 are applicable to the device subject of this submission

Bench Testing: Design verification and validation testing was performed to confirm the system mechanical and software features met specified requirements. Performance testing included verification of the stated operating range and validation of accuracy claims through 20-point COPs and Low Perfusion Pulse Rate and Saturation Accuracy tests. All verification and validation activities met product requirements.

Animal Testing: Animal testing was not required to demonstrate that the proposed device met its design requirements and therefore there are no animal data associated with this device.

Usability / Human Factors

Usability was evaluated with users in simulated operating environments. These studies consisted of formative and summative studies, which demonstrate the device provides adequate assurance of safety and performance (in regards to human factors/usability aspects) for the patient and operator.

Substantial Equivalence

In establishing substantial equivalence of the Bedside Respiratory Patient Monitoring System to the predicate devices, Covidien evaluated the intended use, indications for use, technological characteristics, reported adverse events, and instrument risk profiles. The use of the Bedside Respiratory Patient Monitoring System in patient monitoring environments does not raise any new types of questions of safety and effectiveness compared with the predicate devices currently in use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2012

Covidien
Ms. Elizabeth Malo
Senior Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K121806
Trade/Device Name: Covidien Nellcor™ Bedside Respiratory Patient Monitoring System and the Covidien Nellcor™ Bedside Respiratory Patient Monitoring System with Respiration Rate Software
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, BZQ
Dated: August 31, 2012
Received: September 4, 2012

Dear Ms. Malo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.1 Indications for Use Statement

510(k) Number (if known): K121806

Device Name: Covidien Nellcor™ Bedside Respiratory Patient Monitoring System and the Covidien Nellcor™ Bedside Respiratory Patient Monitoring System Respiration Rate Software

Indications for Use:

For Covidien Nellcor Bedside Respiratory Patient Monitoring System with Respiration Rate Software:

The Nellcor™ Bedside Respiratory Patient Monitoring System is a portable pulse oximeter intended for prescription use only as a continuous non-invasive monitor of arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport. The OxiMax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The Respiration Rate parameter, when used in conjunction with the Nellcor Bedside Respiratory Patient Monitoring System and Nellcor Respiratory Sensor, is intended to be used for the continuous non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)		_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121806